K111211

510(k) Summary of Safety and Effectiveness

DEC 2 2 2011

510(k) Submitter: Streck
7002 South 109th Street
Omaha, NE 68128

Official Correspondent: Bert Moses, Director of Quality
(402)537- 5343

Date Prepared: April 14, 2011

Name of Device:
Trade Name: CELL-DYN 22 Plus Control
Common Name: Assayed Hematology Control
Classification Name: Hematology quality control mixture (864.8625)

Predicate Device: Para 12 Plus (K901875) Manufactured by Streck

Description:
CELL-DYN 22 Plus Control is an in-vitro diagnostic product that contains stabilized human red blood cells, human, mammalian or simulated white blood cells and a platelet component in a preservative medium. The product is packaged in polypropylene plastic vials containing 2.5ml. The closures are polypropylene screw caps with polyethylene liners. There are three different levels (low, normal and high). The vials will be packaged in a six (6) or twelve (12) welled vacuum formed "clam-shell" container with the package insert / assay sheet. The product must be stored at 2 - 10° C.

Intended Use:
CELL-DYN 22 Plus Control is an assayed hematology control for evaluating the accuracy and precision of the CELL-DYN Emerald 22 system.

Assayed parameters include:

WBC (10^9/L), RBC (10^{12}/L), HGB (g/dL), HCT (%), MCV (fL), MCH (pg), MCHC (g/dL), RDW (%), PLT (10^9/L), MPV (fL), NEU (%), NEU (10^9/L), LYM (%), LYM (10^9/L), MON (%), MON (10^9/L), EOS (%), EOS (10^9/L), BAS (%), BAS (10^9/L)

Comparison to Predicate Device:

	Para 12 Plus (Predicate Product)	CELL-DYN 22 Plus Control
Intended Use Statement	Para 12 Plus is an assayed hematology control for evaluating the accuracy and precision of hematology instruments that provide a white blood cell differential.	CELL-DYN 22 Plus Control is an assayed hematology control for evaluating the accuracy and precision of the CELL-DYN Emerald 22 system. Assayed parameters include: WBC (10^9/L), RBC (10^{12}/L), HGB (g/dL), HCT (%), MCV (fL), MCH (pg), MCHC (g/dL), RDW (%), PLT (10^9/L), MPV (fL), NEU (%), NEU (10^9/L), LYM (%), LYM (10^9/L), MON (%), MON (10^9/L), EOS (%), EOS (10^9/L), BAS (%), BAS (10^9/L)
Open Vial Stability	7 days	8 days
Closed Vial Stability	75 days	Same

Reagents	The whole blood reagent may contain any or all of the following: stabilized human or mammalian red blood cells, human, mammalian or simulated white blood cells and a platelet component in a preservative medium.	Same
Storage Conditions	2 - 10°C	Same

Discussion of Tests and Test Results:
Five types of studies were conducted to establish performance of CELL-DYN 22 Plus Control. The five tests conducted were Closed-Vial Stability, Open-Vial Stability, 10-Run Reproducibility, 10-Run Reproducibility compared with Whole Blood and External Site recovery of values. All testing showed that CELL-DYN 22 Plus Control is consistently reproducible, substantially equivalent to the predicate product and stable for the shelf life claimed.

Conclusions Drawn From Tests:
Study results show CELL-DYN 22 Plus Control to be consistently reproducible, substantially equivalent to the predicate products, and stable for the entire product dating. CELL-DYN 22 Plus Control is a safe and effective product, which fulfills its intended use when used as instructed in the product package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Streck Inc.
c/o Ms. Deborah S. Kipp
Quality Assurance Coordinator
7002 South 109th Street
Omaha, NE 68128

DEC 2 2 2011

Re: k111211
Trade/Device Name: CELL-DYN 22 Plus Control
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: Class II
Product Code: GLQ
Dated: December 21, 2011
Received: December 22, 2011

Dear Ms. Kipp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use Form

510(k) Number (if known): K111211

Device Name: CELL-DYN 22 Plus Control

Indications For Use:

CELL-DYN 22 Plus Control is an assayed hematology control for evaluating the accuracy and precision of the CELL-DYN Emerald 22 system.

Assayed parameters include:

WBC (10^9/L), RBC (10^{12}/L), HGB (g/dL), HCT (%), MCV (fL), MCH (pg), MCHC (g/dL), RDW (%), PLT (10^9/L), MPV (fL), NEU (%), NEU (10^9/L), LYM (%), LYM (10^9/L), MON (%), MON (10^9/L), EOS (%), EOS (10^9/L), BAS (%), BAS (10^9/L)

Prescription Use __X__ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

maria m chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111211